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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,917	11/25/2003	James Vig Sherrill	58110.US	6544

408 7590 06/15/2006

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EXAMINER	
SHAW, AMANDA MARIE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,917	SHERRILL ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 25 November 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/17/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-26 have been examined herein.

Claim Objections

2. Claim 4 is objected to because of the following informalities: "locations are arranged" should read "locations arranged". Appropriate correction is required.

Claim 6 is objected to because of the following informalities: "pattern has of the shape" should read "pattern has the shape". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-26 are indefinite over the recitation of the phrase "probe pattern". This phrase in considered unclear because "probe pattern" is not clearly defined in the specification and there is no art recognized definition for this phrase. For example, it is unclear as to whether "probe pattern" refers to a particular shape or if it can mean any arrangement of probes on a slide. Thus the scope of the claim cannot be determined. Additionally the phrase "first pattern" is not clearly defined in the specification and there

is no art recognized definition for this phrase. There is nothing in the specification which explains the difference between the first pattern and the probe pattern. For example, it is unclear as to whether "first pattern" refers to two different types of probes on the sample, or if the probe pattern is every probe on the chip and the first pattern is only the probes which produce a signal. The claims are also indefinite over the recitation of "corresponding to the probe pattern." Corresponding is not an art recognized term to describe the relationship between two patterns. Because the term "corresponding" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to two probe patterns, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Claims 2 is indefinite over the phrase "the probes on the slide". This phrase lacks antecedent basis because it is unclear as to whether this refers to the probes in the probe pattern or the probes in the first pattern.

Claims 3 and 8 are indefinite over the phrase "interlaced first patterns". This phrase is considered unclear because "interlaced first patterns" is not clearly defined in the specification and there is no art recognized definition for this phrase. For example, it is unclear as to whether "interlaced first patterns" refers to a particular arrangement of probes on a slide or if it can mean any arrangement of probes on a slide. Thus the scope of the claim cannot be determined.

Claims 3 is indefinite over the phrase " a plurality of sensors arranged on the detector in the first pattern". This phrase lacks antecedent basis because it is unclear if this is a first pattern for the sensors or the same pattern as the first pattern of the probes.

Claim 6 is indefinite over the phrase "shape of a pie section". This phrase is considered unclear because "shape of a pie section" is not clearly defined in the

specification and there is no art recognized definition for this phrase. For example, a piece of a pie can be any shape (i.e. triangular, circular, square, diamond). Thus the scope of the claim cannot be determined.

Claim 8 is indefinite over the phrase "truncated pie section". This phrase is considered unclear because "truncated pie section" is not clearly defined in the specification and there is no art recognized definition for this phrase. For example, a truncated piece of a pie can be any shape (i.e. triangular, circular, square, diamond). Thus the scope of the claim cannot be determined.

Claim 12 is indefinite over the phrase "certain probes". The claim does not recite the criteria for determining what constitutes the certain probes. Additionally the claim doen not teach how to distinguish these probes from the probes of the probe pattern or the probes of the first pattern. Therefore unclear as to what constitutes the certain probes.

Claim 14 recites the limitation "the form of light". There is insufficient antecedent basis for this limitation in the claim.

Claim 17 and dependent claims recite the limitation "the detection signals". There is insufficient antecedent basis for this limitation in the claim. Also it is unclear as to what is meant by the command signals being controlled by the drive mechanism based in part upon the detection signals. It is unclear as to what is intended to be the relationship between the command signals, drive mechanism and detection signals.

Claims 19 and 20 recite the limitation "the light produced". There is insufficient antecedent basis for this limitation in the claim. Also it is unclear as to whether the "probe pattern including a plurality of subsets" is the same as or distinct from the plurality of probes in a probe pattern.

Claims 20 and 26 recite the limitation "the form of light". There is insufficient antecedent basis for this limitation in the claim.

Claim 22 and 23 are indefinite over the recitation of "data corresponding to the detection signals." Corresponding is not an art recognized term to describe the relationship between data and detection signals. Because the term "corresponding" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to data and detection signals, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Claim 23 is indefinite over the recitation of the phrase "the probes on the slide". It is unclear as to whether this refers to the probes in the probe pattern, probes in the first pattern or both.

Claims 25 and 26 are indefinite over the recitation of "information corresponding to the detection signals." Corresponding is not an art recognized term to describe the relationship between information and detection signals. Because the term "corresponding" has not been clearly defined in the specification and because there is no art recognized definition for this term as it relates to information and detection signals, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 9, 12-15, 17-21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noblett et al (US Patent 6362004) in view of Modlin et al (PG Pub 2001/0034025).

Noblett et al teach an apparatus for reading probes comprising: (i) a substrate platform capable of moving; (ii) a glass slide disposed on the substrate platform; (iii) a first set of probes (i.e. target spots) comprising a plurality of DNA/RNA probes disposed on the slide in a probe pattern (i.e., "a plurality of probes disposed on the slide in a probe pattern"); (iv) a detector for detecting probe signals; (v) a second set of probes arranged in a first pattern which is less dense than the probe pattern (i.e., "a plurality of probes located in a first pattern on the slide"); and (vi) a positioning system for moving the substrate platform in an X-Y plane. Specifically Noblett et al teach that microarrays which have two probe patterns. In the instant case the first pattern is being interpreted as a plurality of dilution spots adjacent to the target spots for use in calibrating the microarray scanning system. The probe pattern is being interpreted as the target spots on the array (Column 5, Fig 2).

Noblett et al do not teach that the apparatus further comprises a housing.

However Modlin et al teach an apparatus for reading probes which further comprises a housing. Modlin et al teach that a housing will substantially enclose the apparatus, forming two protective layers around the continuous high color temperature xenon arc lamp. Additionally a housing permits automated sample loading and switching among light sources and detectors, further protecting the operator from the xenon arc lamp and other components of the system.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Noblett et al so that it further comprised a housing in order to achieve the benefits set fourth by Modlin of providing a protective layers around the continuous high color temperature xenon arc lamp. Further using a housing permits automated sample loading and switching among light sources and detectors, further protecting the operator from the xenon arc lamp and other components of the system.

Regarding Claim 2 Noblett et al teach an apparatus further comprising a plurality of sensors arranged on the detector for detecting probe signals. Specifically Noblett et al teach a detector which has a photomultiplier tubes (Column 4). In the instant case the photomultiplier tube is being interpreted as a detector which comprises a plurality of sensors. Photomultiplier tubes are extremely sensitive detectors of light. Photomultiplier tubes are are constructed from a glass vacum tube which houses a photocathode, several dynodes, and an anode.

Regarding Claim 3 Noblett et al teach an apparatus further comprising a plurality of sensors arranged on the detector for detecting probe signals when aligned with the probes (Column 4 and 5).

Regarding Claim 4 Noblett et al teach that the first pattern and the probe pattern comprise a plurality of locations arranged in rows and columns (See Fig 2)

Regarding Claim 5 Noblett et al teach that the first pattern and the probe pattern comprise a plurality of locations arranged in a rectangular pattern in rows and columns (See Fig 2).

Regarding Claim 9 Noblett et al teach first pattern comprises a plurality of locations arranged in rows and columns wherein at least two different rows have different numbers of locations **or** wherein at least two different columns have a different numbers of locations. Specifically Noblett et al teach that the first pattern has one column with 7 rows and each row has a different location on the slide (See Fig 2).

Regarding Claim 12 Noblett et al teach an analyzer further comprising a source of electromagnetic radiation (light) for illuminating the probes. Specifically Noblett et al teaches that light is used to excite a fluorescent emission from a corresponding fluorophore material which produces an image for each test sample. The images of each spot are then mapped to a corresponding brightness value to determination the expression level of a gene (Column 2).

Regarding Claim 13 Noblett et al teach an analyzer further comprising fiducials (alignment indica) disposed on the slide for aligning the detector (Column 5).

Regarding Claim 14 Noblett et al teach a analyzer further comprising (i) the probe pattern having a plurality of subsets (See Fig 7); (ii) a plurality of sensors arranged on the detector (Column 4); (iii) and one or more fiducials (indicia) disposed of on the slide which produce a signal in the form of light for aligning the detector over the probes (Column 5).

Regarding Claim 15 Noblett et al teach a positioning system comprising a positioning controller which is used to move the substrate platform in an X-Y plane (Column 5).

Noblett et al do not teach a positioning system which is used to move the substrate platform in an X-Y-Z plane.

However Modlin teach an apparatus in which the stage can be moved in the X-Y plane and the optics head can be moved in the Z plane (Para 0141).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Noblett et al so that it further comprised a positioning system which is used to move the substrate platform in an X-Y-Z plane in order to achieve the benefits set fourth by Modlin of providing a positioning system which can move the substrate platform in multiple directions which allows for rapid positioning of the array with high repeatability, while still allowing the array to comprise a large number of available sites.

Regarding Claim 17 Noblett et al teach an apparatus for reading probes comprising: (i) a substrate platform capable of moving; (ii) a glass slide disposed on the substrate platform; (iii) a first set of probes (i.e. target spots) comprising a plurality of DNA/RNA probes disposed on the slide in a probe pattern; (iv) a detector for detecting probe signals; (v) a second set of probes arranged in a first pattern which is less dense than the probe pattern; (vi) a positioning system for moving the substrate platform in an X-Y plane; and (vii) a computational device (i.e. computer) connected to the drive mechanism that controls the movement of the substrate platform by positioning the controller. Specifically Noblett et al teach that microarrays which have two probe patterns. In the instant case the first pattern is being interpreted as a plurality of dilution spots adjacent to the target spots for use in calibrating the microarray scanning system.

The probe pattern is being interpreted as the target spots on the array (Column 5, Fig 2).

Noblett et al do not teach that the apparatus further comprises a housing.

However Modlin et al teach an apparatus for reading probes which further comprises a housing. Modlin et al teach that a housing will substantially enclose the apparatus, forming two protective layers around the continuous high color temperature xenon arc lamp. Additionally a housing permits automated sample loading and switching among light sources and detectors, further protecting the operator from the xenon arc lamp and other components of the system.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Noblett et al so that it further comprised a housing in order to achieve the benefits set fourth by Modlin of providing a protective layers around the continuous high color temperature xenon arc lamp. Further using a housing permits automated sample loading and switching among light sources and detectors, further protecting the operator from the xenon arc lamp and other components of the system.

Regarding Claim 18 Noblett et al teach an analyzer further comprising a computational device that is programmed to move the detector to a first position, receive detection signals and then to move the detector to a second position. Specifically Noblett et al teach that the computational device controls the movement of the substrate platform via the positioning controller and thus functions to position the planar substrate (Column 5). The computational device is programmed to move the

detector to a first position where the image acquired by the detector is sent to the computational device before the computational device moves the detector to a second position (Column 7).

Regarding Claim 19 Noblett et al teach a analyzer further comprising (i) the probe pattern having a plurality of subsets (See Fig 7); (ii) a plurality of sensors arranged on the detector (Column 4); (iii) one or more fiducials (indicia) disposed of on the slide which produce a signal in the form of light for aligning the detector over the probes (Column 5); and (iv) a computational device that is programmed to move the detector to a first position, receive detection signals and then to move the detector to a second position (Columns 5 and 7).

Regarding Claim 20 Noblett et al teach a analyzer further comprising (i) the probe pattern having a plurality of subsets (See Fig 7); (ii) a plurality of sensors arranged on the detector (Column 4); (iii) one or more fiducials (indicia) disposed of on the slide which produce a signal in the form of light for aligning the detector over the probes (Column 5); and (iv) a computational device that is programmed to move the detector to a first position, receive detection signals and then to move the detector to a second position and repetitively issue commands (Columns 5 and 7).

Regarding Claim 21 Noblett et al teach a positioning system comprising a positioning controller which is used to move the substrate platform in an X-Y plane (Column 5).

Noblett et al do not teach a positioning system which is used to the move the substrate platform in an X-Y-Z plane.

However Modlin teach an apparatus in which the stage can be moved in the X-Y plane and the optics head can be moved in the Z plane (Para 0141).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Noblett et al so that it further comprised a positioning system which is used to move the substrate platform in an X-Y-Z plane in order to achieve the benefits set fourth by Modlin of providing a positioning system which can move the substrate platform in multiple directions which allows for rapid positioning of the array with high repeatability, while still allowing the array to comprise a large number of available sites.

Regarding Claim 24 Noblett et al teach a microarray scanning system, comprising a plurality of probe positions. Each position is illuminated independently as it is being addressed by the scanning system. The light source is typically a single-wavelength laser device focused down to form an excitation radiation spot of the desired size (Column 1).

4. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noblett et al (US Patent 6362004) **in view of Modlin et al.**

The teachings of Noblett et al and Modlin et al are presented above.

Regarding Claim 10 Noblett et al teach an analyzer comprising a first pattern of probes.

Noblett et al do not teach that the first pattern comprises a plurality of locations arranged in rows and columns with a different number of locations in each row as

compared to the other rows **and** a different number of locations in each column as compared to the other columns.

However it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the array of Noblett et al so that the first pattern comprises a plurality of locations arranged in rows and columns with a different number of locations in each row as compared to the other rows **and** a different number of locations in each column as compared to the other columns because this arrangement is an equally effective way of arranging a first pattern.

Regarding Claim 11 Noblett et al teach a first pattern and a drive mechanism that is able to move the slide relative to the detector for detecting the probes.

Noblett et al do not teach that the first pattern comprises K number of locations arranged in X number of columns and Y number of rows, and the probe pattern comprises 4K number of locations arranged in 2X number of columns and 2Y number of rows.

However it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the array of Noblett et al so that the first pattern comprised 4K number of locations arranged in 2X number of columns and 2Y number of rows because this arrangement is an equally effective way of arranging a first pattern.

5. Claims 6-8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noblett et al (US Patent 6362004) in view of Modlin et al (PG Pub 2001/0034025) and in further view of Wang et al (US Patent 5922617).

The teachings of Noblett and Modlin are presented above.

Regarding Claims 6-8 Noblett et al teach a first pattern having the shape of a truncated pie section. In the instant case a first pattern in the shape of a truncated pie section is being interpreted as any shape, thus the first pattern taught by Noblett meet this limitation of this claim.

However, Noblett et al do not teach a probe pattern being arranged in a radial orientation on a circular slide.

However, Wang et al teach circular arrays which have probe patterns arranged in a radial orientation (Column 8, Fig 3, 4, 5).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the array of Noblett et al so as to have used a circular array comprising probes arranged radially in order to have achieved the benefits set forth by Wang of using a circular shaped array which can rotate around a central axis in order to accurately detect and differentiate a plurality of positions which are in close physical proximity.

Regarding Claim 16 the combined references do not teach an apparatus further comprising an R drive mechanism for producing rotational motion.

However Wang et al teach an apparatus comprising an R drive mechanism for producing rotational motion. Specifically Wang et al teach a spinning motor rotates the

disk in relation to the scanner to different sites along a given track and a linear motor moves the scanner along a radial direction to scan over the entire disk (Columns 10 and 11).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the array of Noblett et al so as to have used an apparatus comprising an R drive mechanism for producing rotational motion when using a circular array in order to have achieved the benefits set forth by Wang of using a circular shaped array which can rotation around a central axis at various speeds to get a different level of accuracy, so that one can scan very quickly to initially determine sites of interest which may then be scanned more slowly thus allowing for rapid and very reliable detection.

6. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noblett et al (US Patent 6362004) in view of Modlin et al (PG Pub 2001/0034025) and in further view of Sheridan et al (US Patent 6673315).

Regarding Claims 22 and 23, the combined references of Noblett and Modlin do not teach an analyzer further comprising a keypad connected to the data processor for producing signal in response to input from a user, display screen, and a output means.

However Sheridan et al teach an analyzer further comprising a keypad connected to the data processor for producing signal in response to input from a user, a display screen, and a output means such as a print or removable disk drive (Column 6 and Fig 1).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Noblett et al so as to include a keypad connected to the data processor for producing signal in response to input from a user, a display screen, and a output means in order to have achieved the benefits set forth by Sheridan of being able to input commands, analyze, and manipulate data.

7. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noblett et al (US Patent 6362004) in view of Modlin et al (PG Pub 2001/0034025) in view of Sheridan et al (US Patent 6673315), and in further view of Klutzz (PB Pub 2002/0127708).

The teachings of Noblett et al, Modlin et al and Sheridan et al are presented above.

Regarding Claim 25 the combined references teach an analyzer for reading biological probes comprising: a housing, a user input, a display, a slide carriage, a slide, a plurality of probes disposed on the slide in a probe pattern, a plurality of probes disposed on the slide in a first pattern, a detector, a plurality of sensors on the detector, a carriage drive mechanism for moving the slide carriage, and a data processor.

The combined references do not teach a cassette mounted within the housing for extending at least partially out of the housing through the opening in the front wall and for retracting at least partially into the housing through the opening and cassette drive mechanism for moving of the cassette to the first and second positions of the cassette.

However Klutzz et al teach drive system that moves the support structure relative to the bay door between a retracted position and a extended position. The support structure, in the extended position, protrudes into the door opening or even further outwardly, thereby enabling a user to more easily access the support structure and install the test devices on the support structure. When the user has loaded the test devices, they would indicate on the user interface that the support structure has been loaded, whereupon the support structure is withdrawn by the drive system into the bay (Para 0164 and Fig 20).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Noblett et al so that it further comprised a cassette mounted within the housing for extending at least partially out of the housing through the opening in the front wall and for retracting at least partially into the housing through the opening and cassette drive in order to achieve the benefits set fourth by Klutzz of enabling a user to more easily access the support structure and load the test samples on the support structure.

Regarding Claim 26 Noblett et al teach an analyzer further comprising: indicia disposed on the slide, a detector for producing alignment signals and a data processor for receiving the alignment signals.

Conclusion

8. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634
June 12, 2006

CARLA J. MYERS
PRIMARY EXAMINER